

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,          AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps)</b> (See reverse side for instructions)		<b>1. REGISTRATION NUMBER</b> (FDA Establishment Identifier)  FEI: 3011006318	<b>2. REASON FOR SUBMISSION</b> a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input checked="" type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	<b>VALIDATION--FOR FDA USE ONLY</b> VALIDATED BY FDA:19-NOV-2016 DISTRICT: Dallas PRINTED BY FDA:15-DEC-2016	
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<b>PART I - ESTABLISHMENT INFORMATION</b> <b>3. OTHER FDA REGISTRATIONS</b> a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____ <b>4. PHYSICAL LOCATION</b> (Include legal name, number and street, city, state, country, and post office code) AxoGen Corporation  300 Boone Road Suites A2 & A3 Burleson, Texas 76028  a. PHONE 386-462-6800 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		<b>PART II - PRODUCT INFORMATION</b> <b>10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps</b> <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <th rowspan="2" style="width:20%;">Types of HCT / Ps</th> <th colspan="8">Establishment Functions</th> <th rowspan="2" style="width:3%;">11. HCT/Ps DESCRIBED IN 21 CFR 1271.10</th> <th rowspan="2" style="width:3%;">12. 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<b>5. ENTER CORRECTIONS TO ITEM 4</b>  <b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> (Include institution name if applicable, number and street, city, state, country, and post office code) AxoGen Corporation Attn: Mark L. Friedman, Ph.D. 13631 Progress Blvd Suite 400 Alachua, Florida 32615  a. PHONE 386-462-6800 EXT 6820		<b>7. ENTER CORRECTIONS TO ITEM 6</b> b. PHONE _____																																																																																																																																																																																																																																																																																																																												
<b>8. U.S. AGENT</b>  a. E-MAIL _____		<b>9. REPORTING OFFICIAL'S SIGNATURE</b>  a. TYPED NAME Mark L. Friedman, Ph.D. b. E-MAIL mfriedman@axogeninc.com c. TITLE VP of RA&QA d. DATE 18-NOV-2016																																																																																																																																																																																																																																																																																																																												